NOV 23 2011

510(k) Summary

K111748

Applicant [21 CFR 807.92 a(1)]: Pulsar Scientific, LLC
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Device Name [21 CFR 807.92 a(2)]:

Regulation No.:	CFR Part 870.5800
Classification:	Class II
Panel:	870 Cardiovascular
Classification Name:	Compressible Limb Sleeve
Common/usual name:	Intermittent External Pneumatic Compression Device
Product Code:	JOW
Proprietary Name:	Recovery+ and DVTherapy
Model #'s:	PS511 and PS511a

Identification of Predicate Devices [21CFR 807.92 a(3)]:

- DVT Therapy - Doctor's Orders, Inc. DVTcare CA5
  K061125
- DVT Therapy - BioCompression Systems, Bioarterial Plus
  K072666
- Thermal Therapy - ThermoTek, Inc. NanoTherm/VascuTherm
  K061866

Name Clarification

The device as a whole will be marketed as the Recovery+, Model PS511. However, the DVT therapy portion of the device is designed to be portable and used as a stand-alone device. Therefore, the therapy portion of the device is named DVTherapy and assigned Model PS511a. Throughout the submission, when the discussion involves the full device it will be referred to as the Recovery+. When referring to the thermal only portion of the device, it will be referred to as the Recovery+ thermal compression unit. When the

discussion involves the portable DVT therapy portion of the device, it will be referred to as DVTherapy.

Device Description [21 CFR 807.92 a(4)]

Intended Use

The Pulsar Scientific device is not a life-supporting or life-sustaining device. It is a new, prescription use only [21 CFR 801 Subpart D] device for use with restricted mobility and non-ambulatory patients, or other patients as deemed appropriate by the physician. It is not intended for over-the-counter use [21 CFR 801 Subpart C]. The device is intended to function as an intermittent, external pneumatic compression device. The intended therapy of the device is to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding in blood flow back to the heart, to increase blood flow to various body areas, as determined by the physician, to aid in the reduction and control of edema and venous stasis ulcers.

Physical Description

The Recovery+ device is comprised of an electronically controlled, compartmentalized reusable pump used with a variety of single-patient use inflatable anatomical cuffs/wraps. The unit is light-weight and portable. The Recovery+ thermal component with standard pressure component and the DVT component (DVTherapy) of the pump are housed in separate compartments so that they can be used together, separately, or removed for portable usage of the DVTherapy component. For purposes of this application we will refer to the components as the Recovery+ thermal compression unit and the DVTherapy unit.

Therapy Modalities Used

The Recovery+ device is designed to provide compression therapy and/or thermal therapy (cold or hot). The therapies may be used together or separately, as ordered by the physician. The thermal therapy provides chilled or heated fluid to the cuff affixed on an extremity therapy site and compresses the treatment site for optimum performance and fluid transfer. The compression therapy is accomplished by air pumped through the cuffs, which are affixed on an extremity therapy site, to provide intermittent, sequential pressure. This facilitates venous flow towards the center of the body and simulates the muscle contraction and blood flow of ambulation.

Safety Features

The device utilizes microprocessor control with multiple sensors to ensure patient safety and system functionality, and to provide consistent and repeatable therapy modalities. Indicators are both visual on the unit display and audible. Settings are in place to detect

any potentially unsafe situation and to terminate therapy to protect the patient and the system. The unit is light weight and portable. The thermal compression runs only on 115 VAC while the DVT unit can operate on batteries, connected to 115 VAC mains, or while docked in the thermal compression unit. The thermal compression unit has internal power supply while the DVT unit has an external power supply. The unit is protectively housed in a plastic shell, except for the outer membrane switch, the plastic quick-connect locks for tub connection, and an external power supply input jack.

Statement of Intended Use [21 CFR 807.92 a(5)]

The Recovery+ device is used on patient populations for which the Recovery+ device is applicable, based on prescription by a physician.

Indications

Including, but not limited to:

- Decrease the risk of deep venous thrombosis (DVT);
- Aid the blood flow back to the heart;
- Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications;
- Treatment of pain and swelling of acute periarticular processes, treatment of pain and swelling following mobilization of shoulder stiffness under anesthesia, treatment of pain and swelling postoperatively for bones, joints and soft tissue, treatment of pain and swelling caused by musculoskeletal contusions and athletic injury;
- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic edema;
- Reduction of edema associated with soft tissue injuries such as ligament sprains, postoperative edema, and burns.

Contraindications

As with all predicate devices, the device should not be used in the following instances:

- Presumptive evidence of congestive heart failure (CHF)
- Suspected/observed pre-existing deep vein thrombosis (DVT) or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas

- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Suspected/observed patient has Raynaud's Disease
- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Patient therapy contact on extremity containing a fracture
- Extremities that are not sensitive to pain

It is also not recommended that the Recovery+ device be used on a limb where the cuffs would interfere with open wounds, vein ligation, gangrene, dermatitis, recent skin graft, massive edema, or extreme deformity of the leg. They should not be used where increased venous or lymphatic return is undesirable.

Differences in Indications

The indications for the Pulsar Scientific Recovery+ device are generally the same as those published for the predicate devices.

Technological Characteristics [21 CFR 807.92a(6)1]

The technological characteristics of this Recovery+ device are the same in overall design function, materials, energy source, and mode of operation as the predicate units. The material in contact with the patient's skin is medical grade, non-latex, non-woven nylon and polyester, designed for patient comfort and convenience. The inflation/deflation tubes are polyurethane.

The Pulsar Scientific Recovery+ device has the same performance characteristics as the predicate devices. The pneumatic control circuitry is a microprocessor-controlled system. Multiple safety redundancies are built into the system including: high and low temperature indicators, indicators for unit malfunction situations, and system malfunction overpressure safety via a pressure vent valve. Power is supplied via 115 VAC line current, or battery. The surface contact temperature range is microprocessor controlled in cooling from 43^0F to 49^0F and to 105^0F in heating mode.

Testing Conducted

Non-clinical validation, including electromagnetic compatibility (emissions, immunity and safety), mechanical integrity, environmental and life cycle testing, have shown that the Recovery+ has performance characteristics substantially equivalent to or superseding the listed predicate devices. The Recovery+ device has been validated by Pulsar Scientific at a design validation level based on requirement of UL 60601-1, CSA C22.2 NO 601.1 and CENELEC EN 60601-1 and confirmed by an accredited test lab.

Additional bench testing has verified equivalent pressure delivery, cuff fill time, cycle time, temperature management and system operation as the predicate devices listed.

Clinical testing is not appropriate to this device and was therefore not done.

Per the requirements of 21 CR 807, non-clinical validation testing and the information provided in this submission, Pulsar Scientific concludes that the Recovery+ system is safe, effective, and performs in a manner that is substantially equivalent to the predicate devices listed in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pulsar Scientific
c/o Ms. Joy Long
8 Stony Brook Lane
Ludlow, MA 01056

NOV 23 2011

Re: K111748
Trade/Device Name: Recovery+/DVTherapy (Models PS511 and PS511a)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: II
Product Code: JOW
Dated: November 20, 2011
Received: November 23, 2011

Dear Ms. Long:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M.A. Miller

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Pulsar Scientific - 510(k) Number: K111748

Device Name: Recovery+

Indications For Use:

Compression therapy - Including, but not limited to:

- Decrease the risk of deep venous thrombosis (DVT);
- Aid the blood flow back to the heart;
- Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications;
- Treatment of pain and swelling of acute periarticular processes, treatment of pain and swelling following mobilization of shoulder stiffness under anesthesia, treatment of pain and swelling postoperatively for bones, joints and soft tissue, treatment of pain and swelling caused by musculoskeletal contusions and athletic injury;
- Treatment of disorders associate with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic edema;
- Reduction of edema associated with soft tissue injuries such as ligament sprains, postoperative edema, and burns.

Thermal therapy - Including but not limited to:

- Reduction of general edema (swelling);
- Reduction of edema associated with soft tissue injuries such as ligament sprains postoperative edema, and burns;
- Treatment of pain and swelling of acute periarticular processes, treatment of pain and swelling following mobilization of shoulder stiffness under anesthesia, treatment of pain and swelling postoperatively for bones, joints and soft tissue, treatment of pain and swelling caused by musculoskeletal contusions and athletic injury.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hollerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111748